AUDIT REPORT FOR CANADAJUNE 11 THROUGH JULY 6, 2001

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Canada's meat and poultry inspection system from June 11 through July 6, 2001. Nine of the 513 establishments certified to export meat and poultry to the United States were audited. Additionally, two egg establishments were visited. Five of the meat establishments had slaughter operations, one was a boning operation, one was conducting processing operations and the other two were poultry slaughter/processing operations.

The last audit of the Canadian meat inspection system was conducted in April 2000. Eight establishments were audited and all were found acceptable. No system failures were observed during the previous audit and no system failures were observed during the current audit. Three major concerns were reported at that time:

- 1. HACCP plans had no CCP in one establishment visited. *This deficiency was corrected by company and verified by CFIA*.
- 2. Reduced supervisory reviews were observed in one province. *This is a recurring problem, now observed in all three audited provinces.*
- 3. Poor sanitary dressing and sanitizing procedure were observed in several establishments. Although there has been some correction of dressing and sanitizing procedures since the last audit, these deficiencies still need more improvement.

The following species and products are eligible for export to the U.S.:

- Hams and Picnics canned
- Duck, Guinea, and Geese RTC
- Chicken RTC, fresh and processed
- Beef fresh, processed, manufacturing, carcass/cuts, head/tongue, edible organs, canned, cured and processed frozen
- Pork cured, processed, carcass/cuts, fresh, manufacturing, canned and edible organs

- Veal processed, manufacturing, carcass/cuts, fresh, edible organs and canned
- Poultry pies, RTC and specialty
- Turkey processed and RTC
- Sausage
- Varied Combination processed and canned

During January through May of calendar year 2001, Canadian establishments exported 738,404,300 pounds of meat and poultry product to the U.S. Port-of-entry (POE) rejections were for processing defects (350,637 pounds), miscellaneous defects (45,405 pounds), contamination (260,878 pounds), pathological defects (56,473 pounds), and transportation damage and missing shipping marks (114,031 pounds).

PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with Canadian national meat and poultry inspection officials to discuss oversight programs and practices, including enforcement activities. The second entailed an audit of a selection of records in the meat and poultry inspection headquarters facilities preceding the on-site visits. Establishments were randomly selected for records audits and on-site audits. The third was conducted by on-site visits to establishments. The fourth was a visit to two laboratories, one performing analytical testing of field samples for the national residue testing program, and the other culturing field samples for the presence of microbiological contamination with *Salmonella*.

Canada's program effectiveness was assessed by evaluating five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella* species.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials.

RESULTS AND DISCUSSION

Summary

Effective inspection system controls were found to be in place in the nine establishments audited; three establishments (Ests. 401, 545 and 251) were recommended for re-review. Details of audit findings, including compliance with HACCP, SSOPs, and testing programs for *Salmonella* and generic *E. coli*, are discussed later in this report.

As stated above, three major concerns had been identified during the last audit of the Canadian meat inspection system, conducted in April 2000. During this new audit, the auditor determined that the concerns had been addressed and corrected, except regarding the frequency of supervisory reviews.

Supervisory reviews had not been performed monthly in any of the provinces; no supervisory reviews had been performed in any establishment in Manitoba during the last audit. During this new audit, implementation of the required supervisory reviews was again found to be deficient (this was a repeat finding), in all three of the provinces visited. Details are provided in the <u>Enforcement Controls</u> section later in this report.

HACCP deficiencies were found in one establishment (Est. 007). This deficiency was corrected by establishment management.

Entrance Meeting

On June 12, 2001, an entrance meeting was held in the Ottawa offices of the Canadian Food Inspection Agency (CFIA), and was attended by Mr. Donald P. Raymond, National Manager, International Affairs and Retail Food of Animal Origin Division; Dr. Bertrand St-Arnaud, Chief, Export Programs; Mr. Raymond Trotman, Chief, Foreign Country Residue Review Program; Dr. Richard Arsenault, Acting Chief, Meat Processing Inspection Program; Dr. Elaine M. Hendy, Program Audit Officer, Planning, Performance & Program Review Policy, Planning & Coordination Directorate; Mr. Michael Sole, Program Audit Officer, Planning Performance & Program Review Policy, Planning & Coordination Directorate; all from Canadian Food Inspection Agency and Dr. Oto Urban, International Audit Staff Officer, representing FSIS. Topics of discussion included the following:

- 1. The itinerary and lodging arrangements were finalized.
- 2. Species violations and laboratory results were provided to CFIA officials.
- 3. The auditor provided the data-collection instruments he would be employing for compliance with the requirements of Standard Sanitation Operating Procedures, generic *E. coli* testing and the testing for *Salmonella* species.
- 4. The audit procedures and documentation were discussed with CFIA officials.

- 5. The change of the CFIA's upper-level personnel and organizational structure was provided to the auditor.
- 6. The auditor asked about the current state of CFIA's species verification program. This program is currently implemented in processing establishments.
- 7. Development of an animal trace-back program was discussed. This program is now mandatory in Canada.
- 8. The auditor asked about the issue of enforcement of revoking the license of the convicted felon. There is a means to prevent the convicted felon from working in the meat industry again by not issuing a new license.

Headquarters Audit

There had been one change in the organizational structure or upper levels of inspection staffing since the last U.S. audit of Canada's inspection system in April 2000. The office of Vice-President was created.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. specifications. The FSIS auditor (hereinafter called "the auditor") observed and evaluated the process.

The auditor conducted a review of inspection system documents pertaining to the establishments listed for records review. This records review was conducted at the headquarters. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the U.S.
- Label approval records such as generic labels, and animal raising claims.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory analyses for residues.
- Pathogen reduction and other food safety initiatives such as SSOPs, HACCP programs, generic *E. coli* testing and *Salmonella* testing.
- Sanitation, slaughter and processing inspection procedures and standards.
- Control of products from livestock with conditions such as tuberculosis, cysticercosis, etc., and of inedible and condemned materials.
- Export product inspection and control including export certificates.
- Enforcement records, including examples of criminal prosecution, consumer complaints, recalls, seizure and control of noncompliant product, and withholding,

suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

The following concerns arose as a result the examination of these documents.

The data collection for SSOP indicated the following observations:

- 1. The auditor was unable to assess SSOPs of Ests. 30 and 202, because the IIC had not adopted the use of amended form.
- 2. The used form did not allow us to distinguish between pre-operational and operational sanitation in Ests. 7, 147, 58, 128, and 14.

The data collection for HACCP indicated the following observations:

- 1. HACCP plan for meat portioning did not have CCP in Est. 128.
- 2. In Est. 202, parts 1 and 2 of the HACCP program covering questions 1 through 4 were not provided to auditor.
- 3. In all HACCP documents provided, the pre-shipment review was not done systematically but was being performed during verification control procedure.

Ests. 373 and 109 were not eligible to export product to the U.S and Est. 211 did not provide any documentation.

Government Oversight

All inspection veterinarians and inspectors in establishments certified by Canada as eligible to export meat and poultry products to the United States were full-time CFIA employees, receiving no remuneration from either industry or establishment personnel.

Establishment Audits

Four hundred twenty-seven establishments were certified to export meat and poultry products to the United States at the time this audit was conducted. Nine establishments were visited for on-site audits. In all nine establishments visited, both CFIA inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of products.

During this audit of the Canadian Inspection System, the auditor also visited two U.S. exporting egg-processing establishments.

Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information was also collected about

the risk areas of government oversight of private laboratory; intralaboratory quality assurance procedures, including sample handling; and methodology.

The Centre for Veterinary Drug Residues Laboratory in the Canadian Food Inspection Agency in Saskatoon, Saskatchewan was audited on June 26, 2001. Except as noted below, effective controls were in place for sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions. The methods used for the analyses were acceptable. No compositing of samples was done (this was not a deficiency).

• The residue analysis laboratory in Saskatoon was performing intra-laboratory and interlaboratory check samples but did provide the names of analysts.

Canada's microbiological testing for *Salmonella* was being performed in private laboratories. One of these, the Laboratoire d'environnement S.M. inc. in Varennes, Quebeck was audited. The auditor determined that the system met the criteria established for the use of private laboratories under FSIS's Pathogen Reduction/HACCP rule. These criteria are:

- 1. The laboratories have been accredited by the CFIA's Standard Counsel of Canada.
- 2. The laboratories have properly trained personnel, suitable facilities and equipment, a written quality assurance program, and reporting and record-keeping capabilities.
- 3. Results of analyses are being reported simultaneously to the government and establishment.

The method for testing for *E. coli* O157:H7 used by FSIS has not been approved by Health Canada, so it has not been used by CFIA.

Establishment Operations by Establishment Number

The following operations were being conducted in the nine meat and poultry establishments:

Beef slaughter, boning, cutting, and grinding - Est.38.

Pork slaughter, boning, and cutting – Est. 604.

Pork slaughter, boning, cutting, and grinding (Japan only) – Est.270A.

Beef slaughter – Est.401.

Chicken, Duck, and Turkey, slaughter, boning and grinding - Est. 599.

Chicken slaughter, boning, and cutting – Est.545.

Pork slaughter and cutting – Est.129.

Pork boning and grinding – Est.75.

Shelf stable and non-shelf stable canned product – Est.251.

Two egg product establishments (20 and 22) were also visited.

SANITATION CONTROLS

Based on the on-site audits of establishments, Canada's inspection system had controls in place for water potability records, chlorination procedures, back siphonage prevention, sanitizers, establishment separation, temperature control, lighting, inspector work place, ventilation, facilities approval, over-product ceiling, product contact equipment, other product areas, dry storage areas, antemortem facilities, personal dress and habits, product reconditioning, product transportation and waste disposal.

Sanitation Standard Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOPs were found to meet the basic FSIS regulatory requirements, with only occasional minor variations.

- 1. Preventive action was not recorded in the establishment SSOP program in Ests.604, 270A, 401, 599, 545, 129, 75, and 251. *This will be corrected immediately in all establishments*.
- 2. In Est.604, procedures did not address the cleaning of food-contact surfaces of facilities, equipment, and utensils. *This was included in records*.
- 3. The procedure was not signed in Est.599. *It was corrected immediately*.

Cross-Contamination

- 1. Swine carcasses were being contaminated as a result of direct contact with the employee's boots during the dressing operation in Est. 129. *This deficiency was corrected immediately by the establishment management.*
- 2. Identified edible barrel was being used by birds hangers in the slaughter area as an inedible barrel in Est. 545. *Corrected immediately by the establishment employee*.
- 3. The loose tape was observed over the chiller in Est. 545. *This was scheduled for correction*.

Over-Product Equipment

1. Condensation was observed on the hanging spider web in the deboning room, directly above edible empty combo in Est. 129. *The combo was moved by a company employee*.

- 2. Heavy condensation was observed on overhead equipment, which was dripping directly over carcasses in the carcass holding cooler in Est. 401. *This deficiency was corrected by the establishment management.*
- 3. Heavy condensation was dripping from overhead structures onto packaged boxes of product in the shipping cooler (the company employee did not follow the supervisory command) in Est. 545. *This deficiency was corrected immediately by the establishment management.*
- 4. In Est. 545, dripping condensation from overhead structures was observed over the edible product conveyor belt in the boning and cutting room. *Management officials took immediate corrective action.*
- 5. Dripping condensation was observed over the salvaging table in the salvage operation room in Est. 545. *The CFIA official ordered immediate corrective action*.
- 6. Rusty overhead pipes over the chiller were observed in the chill room in Est. 545. *This deficiency was scheduled for correction.*
- 7. In Est. 75, condensation was observed over plastic covered combos of product in the finished product cooler. *Combos were moved to a different location by an establishment employee*.
- 8. Non-dripping condensation was observed over carcasses in a carcass holding cooler and over product in the shipping area in Est.129. *This deficiency was corrected by an establishment employee*.

Sanitary Dressing Procedures

- 1. In Est. 270A, ingesta contamination was observed in 1 of approximately 40 offals in the kill floor. *This deficiency was observed by the auditor and corrected by the establishment officials.*
- 2. Hide puller was observed leaving marks on few carcasses in the carcass cooler in Est. 401. *This deficiency was corrected immediately by the company employee.*

Product Handling and Storage

- 1. Grease and rail dust were observed on carcasses in the cooler in Est.38. *This was corrected immediately by the establishment employee*.
- 2. Grease was observed on two carcasses on the kill floor in Est.604. *Corrected by establishment.*
- 3. Grease was observed on two carcasses in the cooler in Est.270A. *It was corrected immediately by establishment*.

- 4. In Est.401, offals were not spaced out in the cooler. *Corrected immediately by the management*.
- 5. Rail dust was present on two carcasses in the shipping dock in Est.401. *Corrective action was immediate.*
- 6. Ice build-up was observed on boxed product in the freezer in Est.545. *This deficiency was scheduled for correction*.
- 7. In Est.129, a plastic-covered combo had several cuts, as well as oil spots and water on the outside of the plastic. *This deficiency was corrected by the establishment employees*.
- 8. Grease was observed on the cut plastic covering the combos in the finished product cooler and boning room in Est.75. *This deficiency was corrected by establishment management.*

Equipment Sanitizing

The employee at the bird salvage station did not sanitize her knife during the operation in Est.545. *This deficiency was corrected by the CFIA reviewer*.

Hand Washing Facilities

In Est.251, the waste containers had hand-operated covers in the men's and women's bathrooms. *These covers were removed by company management.*

Maintenance Program

- 1. The floor in the cut up area needs to be repaired in Est.270A. *This was scheduled for correction*.
- 2. In Est.599, the dirty, old vent pipe with hanging spider webs from the ceiling was observed over the product traffic way in the chiller and boning room. *This was scheduled for correction by the establishment officials*.
- 3. The water spray on the viscera puller was not efficient in Est. 599. *Corrected immediately by an establishment employee*.
- 4. Large holes under the door leading to the shipping dock with outside premises were observed in Est.129. *This was scheduled for correction*.

Pre-Operational Sanitation

Dirty pieces of plastic were observed inside the cooler's refrigeration unit in Est. 599. *This deficiency was corrected immediately by the reviewer*.

Operational Sanitation

- 1. Squeegee used for floor cleaning was stored on the can washer in Est. 251. *It was removed by the CFIA IIC*.
- 2. The equipment and barrels used for edible product were not washed adequately in Est. 251. *This deficiency was corrected by the company and CFIA IIC*.

Personnel Hygiene and Practices

- 1. An employee was observed picking up a frock from the floor and hanging it back for further use in the deboning room in Est.38. *This deficiency was corrected immediately by a company employee.*
- 2. In Est. 38, gloves, a street bag and coats were found on the floor in the pelletizing area. *This was corrected immediately by the establishment employees*.
- 3. Gloves and aprons were found on the floor in several areas of Est.38. *This deficiency was corrected immediately by an establishment employee.*
- 4. An employee was observed failing to wash his hands before continuing to work with product after contaminating them by touching the floor in Est. 599. *The establishment officials took immediate corrective action*.

Pest Control

- 1. There was documentation of the continuous presence of mice in several areas of Est.38, but no preventive action was recorded. *Future corrective action was scheduled*.
- 2. Flies were observed on the kill floor in Est.604. *Management tried to find out how the insects were accessing the kill floor*.
- 3. In Est.270A, a fly was observed on the kill floor. *Establishment management took corrective action*.
- 4. In Est.270A, the findings of pest/rodent inspection were not clearly recorded. *The establishment will ask the person performing the rodent control to clarify his findings*.
- 5. Rodent control box was missing in the box room in Est.75. *This deficiency was investigated by the company management and corrective action was scheduled.*
- 6. In Est.75, the documented vermin control records did not have corrective actions reported. *Corrective action was scheduled by the establishment*.

Operations Work Space

In Est.251, workplaces were congested in some areas, making it difficult to prevent cross-contamination of product. *Scheduled for correction*.

Welfare facilities

- 1. Employees' street and work clothing was not properly separated in Est.599. *This deficiency was corrected by company management.*
- 2. Employees' aprons were found on the floor in the men's locker room in Est.545. *Corrected immediately by establishment management.*
- 3. In Est.545, four out of seven toilets were not functional in the women's bathroom. Two of them were made functional during the audit process; the other two were scheduled for repair.
- 4. A company employee's street clothes were observed on the top of the dressing cabinet in the women dressing room in Est.251. *This deficiency was corrected by the establishment management.*

Outside Premises

- 1. The outside premises of Est. 604 had some areas of accumulated waste, like used coffee cups, etc. *This was corrected by the establishment management.*
- 2. In Est.401, the outside premises had waste materials in several areas around the animal pens. *No corrective action was observed.*
- 3. The outside premises of Est. 599 had waste material in several areas. *Corrective action was scheduled*.

ANIMAL DISEASE CONTROLS

With the exceptions listed below, Canada's inspection system had controls in place to ensure adequate animal identification, ante-mortem and post-mortem inspection procedures and dispositions, and procedures for sanitary handling of returned and rework product.

- 1. Condemned product is not properly identified and denatured before being taken to rendering in Est.38. The establishment claims that the rendering company doesn't accept denatured hide. *This procedure is going to change by identifying animal by ear tag*.
- 2. There was no identification and denaturing of carcasses in Ests.604, 401 and 270A. *The CFIA officials asked for carcass identification.*

3. In Est.129, the decharacterized carcasses were observed in the edible combo in the cooler. *This was immediately corrected by the establishment management.*

There were reported to have been no outbreaks of animal diseases with public-health significance since the previous U.S. audit. Canada is free of diseases from A & B list of reportable diseases. The only animal disease with public health significance present currently in some localized areas of the country is tuberculosis. Tuberculosis and brucellosis exists in certain locations in wild life population.

There was a visit to a feedlot in Lakeside, Alberta. Feedlot cows were separated by breed and weight. Feedlot veterinarians were responsible for checking all animals. They were checking treatment protocol for animal diseases. The tagging of animals is performed by the company, and will be performed in the future by the government. The animal trace-back system is fully developed and functioning in beef.

RESIDUE CONTROLS

Canada's National Residue Testing Plan for 2001 was being followed, and was on schedule. Except as noted below, the Canadian inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals

There was a visit to a feed mill in Lakeside, Alberta. Tylosin and Monensin are the only drugs tested. There is a laboratory with 15 analysts on site performing testing mostly for nutrients but also for generic *E. coli* for CFIA and *E. coli* O157:H7 for customers. The company takes the sample and suppliers are required to pay for samples. The company manager is checking for withdrawal period for drugs before the slaughter under veterinary control. Feed is medicated by mixing, directly on the truck and every load is sampled. There was inspection of the mill for BSE in 1997. The CFIA samples feed for chemical and biological contamination at feed mills. "Feed Act" allows the Agency to register specific feed. Health Canada has the prime responsibility for product medication and for registering drugs. CFIA verifies feed mills and farms by using:

- A) Sampling program-testing feed of the appropriate level of drug.
- B) Random program testing for drugs in non-medicated feed.

The residue-sampling program was not under lock and key in the inspection room in Est.401. *This deficiency was corrected immediately by CFIA.*

SLAUGHTER/PROCESSING CONTROLS

Except as noted below, the Canadian inspection system had controls in place to ensure adequate animal identification, antemortem inspection procedures, antemortem disposition,

humane slaughter with proper animal handling, postmortem inspection procedures, and postmortem disposition.

Can Filling Procedures

The improper closure detector for sealing of glass containers was malfunctioning in Est.251. *This detector was checked by the company technician.*

Post-processing Handling

In Est.251, the control on the recycling cooling water was not present. *Discussed during the exit meeting and the company agreed to change their practices.*

HACCP Implementation

All establishments approved to export meat and poultry products to the U.S. are required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

The HACCP programs were found to meet the basic FSIS regulatory requirements. The following deficiencies were observed during the on-site audit:

- 1. "Zero tolerance" for fecal contamination was not defined in Est.401; critical limits allowed fecal contamination of carcasses.
- 2. The HACCP critical limits for "zero tolerance" for fecal contamination were not identified in Est.545.
- 3. On-site HACCP verification was performed once a month in Est.129.
- 4. HACCP on-site verification on product receiving was performed only once a year by the company in Est.75.
- 5. The pre-shipment review was performed only in Ests.38 and 251. The rest of audited establishments were not aware of this requirement.
- 6. The HACCP critical limits need to be specified in Est.251.

Testing for Generic E. coli

Canada has adopted the FSIS regulatory requirements for generic E. coli testing.

Seven of the nine establishments audited were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing, and were audited and evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

The generic *E. coli* testing programs were found to meet the basic FSIS regulatory requirements. The following deficiencies were observed:

- 1. The method used for generic *E. coli* testing was not random and upper/action limit was not identified. *Corrected immediately by the establishment officials in Est.270A*.
- 2. Improper testing and evaluation of generic *E. coli* was found in Ests.38 and 401. Sponging method was used for sample collection, excision method was used for evaluation of the test results but no numerical values were found. In Ests. 38 and 401, no baseline studies for generic *E. coli* had been conducted, and no statistical process control had been developed for evaluation of the results as required. *The Auditor discussed the requirement with the Canadian officials, both in the establishments and during the country exit meeting. The officials stated that they would confer with International Policy Staff regarding clarification of the equivalence of the sampling procedures.*
- 3. The random method of carcass selection for generic *E. coli* was not being performed in Est.599. *The company reluctantly scheduled this deficiency for correction.*

Additionally, establishments had adequate controls in place to prevent meat/poultry products intended for Canadian domestic consumption from being commingled with products eligible for export to the U.S.

ENFORCEMENT CONTROLS

Inspection System Controls

Except as noted below, the Canadian inspection system controls [ante-and post-mortem inspection procedures and dispositions, control of restricted product and inspection samples, control and disposition of dead, dying, diseased or disabled animals, boneless meat reinspection, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, monitoring and verification of establishment programs and controls (including the taking and documentation of corrective actions under HACCP plans), inspection supervision and documentation, the importation of only eligible livestock or poultry from other countries (i.e., only from eligible countries and certified establishments within those countries), and the importation of only eligible meat or poultry products from other counties for further processing] were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

- 1. Proper carcass identification (stamping) was not visible on many carcasses in Est.38. *Corrective action was scheduled.*
- 2. Carcass stamping was not legible on several carcasses in the carcass cooler in Est.401. *Management officials gave assurances that the problem would be corrected.*

Testing for Salmonella Species

Seven of the establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

The following deficiencies were observed during this audit:

- 1. Carcasses were not selected randomly for Salmonella testing in Est.270A. *Corrected immediately by the establishment officials*.
- 2. Carcass selection for Salmonella testing was not being followed in Est. 599. *This was scheduled for correction by the company.*

Canada has adopted the FSIS regulatory requirements for *Salmonella* testing with the exception of the following equivalent measures:

- 1. SAMPLE COLLECTOR: Establishment Takes Samples. The criteria used for equivalence decisions for use of establishment employees in lieu of government employees are:
 - There is a clearly written sampling plan with instructions for sample collection and processing that will be universally followed.
 - The government has a means of ensuring that establishment sample collection activities are appropriate.
 - The government uses test results to monitor establishment performance over time.
 - The government takes immediate action any time an establishment fails to meet Salmonella performance standards.
- 2. LABORATORIES: Private Laboratories. The criteria used for equivalence decisions for the use of private laboratories in lieu of government laboratories are:
 - The laboratory is accredited/approved by the government, accredited by a third-party accrediting organization with oversight by the government, or a government contract laboratory.
 - The laboratory has properly trained personnel, suitable facilities and equipment, a written quality assurance program, and reporting and record-keeping capabilities.
 - Results of analyses are reported to the government or simultaneously to the government and the establishment.

Species Verification Testing

At the time of this audit, Canada was not exempt from the species verification-testing requirement. The auditor verified that species verification testing was being conducted in processing but not in slaughter establishments in accordance with FSIS requirements. Every sixth sample in ready-to-eat product is sampled for species verification.

Monthly Reviews

These reviews were being performed by the Canadian Food Inspection Agency supervisor equivalent of Circuit Supervisors. Some were veterinarians with many years of experience.

The internal review program was applied equally to both export and non-export establishments. Internal review visits were not announced in advance, and were conducted, at times by the CFIA individuals not team. The records of audited establishments were kept in the inspection offices of the individual establishments, and copies were also kept in the Area office, and the central Canada offices in Ottawa, and were routinely maintained on file for a minimum of 10 years.

After observing the internal reviewers' activities in the field, the auditor was confident in their professionalism, thoroughness, and knowledge of U.S. requirements, and in the effectiveness of Canada's internal review program as a whole.

The only exception was the "monthly supervisory reviews", which are considered to be inspections of the establishment by a program officer stationed usually at the regional or area office. Unlike the U.S., the CFIA has divided the supervision of inspection activities into two linked areas:

- 1. Operational supervision of staff (leave scheduling, grievances and personnel issues).
- 2. Program function supervision (clarification of program requirements and verification of program delivery).

The Animal Products (Meat Hygiene) Program Network officer who exercises functional program supervision for the establishment receives a copy of Form 1427 completed by the inspection-in-charge at the establishment. Inspectors are instructed to contact the program officer whenever a program issue is identified and whenever an establishment rating modification is required. Based on the existence of these controls, the CFIA reduced the number of formal supervisory visits from 11 per year to four per year. This reduction took place over a number of years. The only province that did not perform any supervisory reviews in the last years was Manitoba.

Presently, the monthly supervisory reviews are done quarterly in provinces of Alberta, British Columbia and between one to three times a year in slaughter establishments in Ouebec.

Enforcement Activities

Canada's laws contain authorities at least equivalent to United States for enforcement of their meat and poultry acts, with the exception:

The Canadian constitution prohibits discrimination against people who have a past conviction but who have completed the conditions of their sentence and have been rehabilitated. For this reason, the Canadian Food Inspection Agency cannot apply licensing restrictions on individuals with past convictions for felony or misdemeanor. The CFIA would treat any situation where there were concerns that an operator might potentially operate out of compliance with legislative requirements as a serious matter and would adjust CFIA inspection activities at such establishments accordingly.

All establishments in Canada exporting to the U.S. are currently operating under HACCP systems. When a registered establishment wants to export meat or poultry products to the United States, they must meet the U.S. regulatory requirements for HACCP, generic *E. coli*, and *Salmonella* performance standards. These regulatory requirements are contained in Canada's Meat Hygiene Manual. Canada had conducted pre-requisite programs that included: premises, transportation and storage, equipment, personnel, sanitation and pest control, and recalls, followed by HACCP "recognition" activities.

Exit Meetings

An exit meeting was conducted in Ottawa on July 6, 2001. The participants included Dr. Mervyn F. Baker, Director, Food of Animal Origin Division (FAOD), Animal Products Directorate (APD), CFIA; Dr. Bertrand St-Arnaud, Chief, Export Programs, FAOD, APD; Dr. Richard Arsenault, Acting Chief, Meat Processing Inspection Program, FAOD, APD; Dr. Elaine M. Hendy, Program Audit Officer, Planning, Performance & Program Review Policy, Planning & Coordination Directorate; Mr. Michael Sole, Program Audit Officer, Planning Performance & Program Review Policy, Planning & Coordination Directorate; Dr. Jean Kamanzi, Chief, Program Development and Evaluation, Foodborne Pathogen Unit Food Laboratory, Laboratory Services Division, Food inspection Directorate, CFIA; Dr. Wayne Outhwaite, Acting Director, Operations Coordination Division, CFIA; Ms. Judy Scaife, Chief, Processed egg Inspection Programs, FAOD, APD, CFIA; Dr. Christiane Allard, Program Specialist, Food of Origin Network (Quebec), APD, CFIA; Dr. Loise Carriere, Veterinary Control Officer, Animal Health Division, APD, CFIA; Mr. Sergio Tolusso, Program Officer, Feed Division, APD, CFIA and Dr. Oto Urban, International Audit Staff Officer, FSIS. The following topics were discussed:

- 1 CFIA reduced supervisory reviews, four per year in Alberta and British Columbia, and one to three per year in slaughter establishments in Quebec. *This topic will be discussed with IPD*.
- 2 The *E. coli* and *Salmonella* carcass selection was not following random selection in Ests.599 and 270A.

- 3 "Zero tolerance" for fecal contamination was not defined in Ests.401 and 545; the critical limits allowed fecal contamination of carcasses.
- 4 The detector for sealing of glass containers was malfunctioning in Est.251. *This detector was checked by company technician.*
- 5 There was no identification and denaturing of carcasses performed in Ests.38, 604, 401 and 270A. *The CFIA officials asked for carcass identification*
- 6 The employee at the bird salvage station did not sanitize her knife during the operation in Est.545. *This deficiency was corrected by the CFIA reviewer*.
- 7 Several sanitary deficiencies such as condensation, which were corrected by establishments' management.

CONCLUSION

The inspection system of Canada was found to have effective controls to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments. Nine establishments were audited: six were acceptable, and three were evaluated as acceptable/re-review. The deficiencies encountered during the on-site establishment audits, in those establishments which were found to be acceptable, were adequately addressed to the auditor's satisfaction. Two egg establishments were visited during this review. Inspection verification procedures, process verification, control of inedible egg products, *Salmonella* surveillance testing program, and oversight of egg products inspection system were reviewed and found to be satisfactory.

Previous deficiencies reported (calibration of thermometers, positive pressure and pour tests) were corrected.

Dr. Oto Urban International Audit Staff Officer (signed) Dr. Oto Urban

ATTACHMENTS

- A. Data collection instrument for SSOPs
- B. Data collection instrument for HACCP programs
- C. Data collection instrument for E. coli testing
- D. Data collection instrument for Salmonella testing
- E. Laboratory Audit Forms
- F. Individual Foreign Establishment Audit Forms
- G. Written Foreign Country's Response to the Draft Final Audit Report

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

- 1. The establishment has a written SSOP program.
- 2. The procedure addresses pre-operational sanitation.
- 3. The procedure addresses operational sanitation.
- 4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
- 5. The procedure indicates the frequency of the tasks.
- 6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
- 7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
- 8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

	1.Written	2. Pre-op	3. Oper.	4. Contact	5. Fre-	6. Respons-	7. Docu-	8. Dated
	program	sanitation	sanitation	surfaces	quency	ible indiv.	mentation	and signed
Est. #	addressed	addressed	addressed	addressed	addressed	identified	done daily	
38	V	$\sqrt{}$	√	√	V	V	V	\checkmark
604	V	$\sqrt{}$		No	V	V	√*	$\sqrt{}$
270A	V	$\sqrt{}$		V	V	V	√*	$\sqrt{}$
401	V	$\sqrt{}$	√	√	V	V	√*	\checkmark
599	V	$\sqrt{}$	√	V	V	V	√*	No
545	V	$\sqrt{}$	√	V	V	V	√*	$\sqrt{}$
129	V	$\sqrt{}$	√	V	V	V	√*	$\sqrt{}$
75	V	$\sqrt{}$	√	√	V	V	√*	√
251	V	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	V	V	$\sqrt{*}$	$\sqrt{}$

- .
- Preventive action was not recorded in the establishment SSOP program in Ests.604, 270A, 401, 599, 545, 129, 75, and 251. This will be corrected immediately in all establishments.
- In Est.604, procedures did not address the cleaning of food-contact surfaces of facilities, equipment, and utensils. This was included in records.
- The procedure was not signed in Est.599. It was corrected immediately.

Documentation was also audited from the following establishments that were not visited onsite, during the centralized document audit:

	1.Written	2. Pre-op	3. Oper.	4. Contact	5. Fre-	6. Respons-	7. Docu-	8. Dated
	program	sanitation	sanitation	surfaces	quency	ible indiv.	mentation	and signed
Est. #	addressed	addressed	addressed	addressed	addressed	identified	done daily	
7	$\sqrt{}$	√*	√*	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	\checkmark
147		√*	√*	$\sqrt{}$	V	V	V	$\sqrt{}$
58		$\sqrt{*}$	$\sqrt{*}$	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	V	$\sqrt{}$
128	$\sqrt{}$	$\sqrt{*}$	$\sqrt{*}$	\checkmark	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$
30	No	No	No	No	No	No	No	No
202	No	No	No	No	No	No	No	No
14	$\sqrt{}$	√*	√*	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	\checkmark

The data collection for SSOP indicated following observations:

- ♦ The auditor was unable assess SSOP s of Ests. 30 and 202, because the IIC had not adopted the use of amended form.
- ♦ The used form did not allow us to distinguish between pre-operational and operational sanitation in Ests. 7, 147, 58, 128, and 14.
- Ests. 373 and 109 were not eligible to export product to the U.S.
- ♦ Documents were not received from Est.211.

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

- 1. The establishment has a flow chart that describes the process steps and product flow.
- 2. The establishment has conducted a hazard analysis that includes food safety hazards likely to occur.
- 3. The analysis includes the intended use of or the consumers of the finished product(s).
- 4. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
- 5. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
- 6. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
- 7. The plan describes corrective actions taken when a critical limit is exceeded.
- 8. The HACCP plan was validated using multiple monitoring results.
 - 9. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
- 10. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
- 11. The HACCP plan is dated and signed by a responsible establishment official.
- 12. The establishment is performing routine pre-shipment document reviews.

The results of these evaluations were as follows:

Est.#	1. Flow diagram	2. Haz- ard an- alysis conduct -ed	3. Use & users includ- ed	4. Plan for each hazard	5. CCPs for all hazards	6. Monitoring is specified	7. Corr. actions are des- cribed	8. Plan valida- ted	9. Adequate verific. Procedures	10.Ade- quate docu- menta- tion	11. Dated and signed	12.Pre- shipmt. doc. review
38	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	\checkmark	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	\checkmark	\checkmark	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$
604	√	V	√	√	V	V	√	V	V	√	√	No
270A	√	√	√	√	√	√	√	√	√	√	√	N
401	√	√	√	√	√	No	√	√	√	No	√	N
599	√	√	√	√	V	√	√	√	√	√	√	N
545	√	√	√	√	√	No	V	√	√	√	√	N
129	√	√	√	√	V	√	√	√	√*	√	√	N
75	√	√	√	√	V	√	√	√	√*	√	√	N
251	√	√	√	√	√	N	V	√	√	√	√	√

- "Zero tolerance" for fecal contamination was not defined in Est.401, critical limits allowed fecal contamination of carcasses and inadequate rating system was used.
- The HACCP critical limits for "zero tolerance" for fecal contamination were not identified in Est.545.
- On-site HACCP verification was performed once a month in Est. 129.
- HACCP on-site verification on product receiving was performed only once a year by the company in Est.75.

- The pre-shipment review was performed only in Ests.38 and 251. The rest of audited establishments were not aware of this requirement.
- The HACCP critical limits need to be specified in Est.251.

Documentation was also audited from the following establishments that were not visited on-site, during the centralized document audit:

Est.#	1. Flow diagram	2. Haz- ard an- alysis conduct -ed	3. Use & users includ- ed	4. Plan for each hazard	5. CCPs for all hazards	6. Mon- itoring is spec- ified	7. Corr. actions are des- cribed	8. Plan valida- ted	9. Adequate verific. Procedures	10.Ade- quate docu- menta- tion	11. Dated and signed	12.Pre- shipmt. doc. review
7	\checkmark	$\sqrt{}$							$\sqrt{}$		\checkmark	No
147	√		√	√	V	V	√					No
58	√	√	√	√	√	√	√	√	\checkmark	√	√	No
128	\checkmark	$\sqrt{}$	√	√	√	No	√		$\sqrt{}$	√	\checkmark	No
30	√	$\sqrt{}$	√	√	√	√	√		$\sqrt{}$		\checkmark	No
202	No	N	N	N	V	√	V	√	√	√	√	N
14	√	√	√	√	V	√		√	√	√	√	N

The data collection for HACCP indicated following observations:

- HACCP plan for meat portioning did not have CCP in Est. 128.
- In Est. 202, parts 1 and 2 of the HACCP program covering questions 1 through 4 were not provided to auditor.
- In all HACCP documents provided, the pre-shipment review is not done systematically but is performed during verification control procedure.
- Ests. 373 and 109 were not eligible to export product to the U.S.
- ♦ Documents were not received from Est.211.

Data Collection Instrument for Generic E. coli Testing

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

- 1. The establishment has a written procedure for testing for generic *E. coli*.
- 2. The procedure designates the employee(s) responsible to collect the samples.
- 3. The procedure designates the establishment location for sample collecting.
- 4. The sample collection is done on the predominant species being slaughtered.
- 5. The sampling is done at the frequency specified in the procedure.
- 6. The proper carcass site(s) and/or collection methodology (sponge or excision) is/are being used for sampling.
- 7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
- 8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
- 9. The results of the tests are being recorded on a process control chart showing the most recent test results.
- 10. The test results are being maintained for at least 12 months.

	1.Writ-	2. Samp-	3.Samp-	4. Pre-	5. Samp-	6. Pro-	7. Samp-	8. Using	9. Chart	10. Re-
	ten pro-	ler des-	ling lo-	domin.	ling at	per site	ling is	AOAC	or graph	sults are
Est. #	cedure	ignated	cation	species	the req'd	or	random	method	of	kept at
			given	sampled	freq.	method			results	least 1 yr
38		$\sqrt{}$		N/A	$\sqrt{}$	$\sqrt{}$			$\sqrt{}$	$\sqrt{}$
604		√		N/A	√		√			$\sqrt{}$
270A				N/A			No		No	$\sqrt{}$
401		√		N/A	√		√		No	$\sqrt{}$
599		√		$\sqrt{}$	√		No			$\sqrt{}$
545	√	√	√	N/A	√	√	√	√		$\sqrt{}$
129		√		N/A	√		√			$\sqrt{}$
75	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
251	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

- The method used for E. coli testing was not random and upper/action limit was not identified. Corrected immediately by the establishment officials in Est.270A.
- Improper testing and evaluation of E. coli was found in Ests.38 and 401. Sponging method was used for sample collection, excision method was used for evaluation of the test results but no numerical values were found.
- The E. coli carcass selection was not following random selection in Est. 599.

Documentation was also audited from the following establishments that were not visited onsite, during the centralized document audit:

	1.Writ-	2. Samp-	3.Samp-	4. Pre-	5. Samp-	6. Pro-	7. Samp-	8. Using	9. Chart	10. Re-
	ten pro-	ler des-	ling lo-	domin.	ling at	per site	ling is	AOAC	or graph	sults are
Est. #	cedure	ignated	cation	species	the req'd	or	random	method	of	kept at
			given	sampled	freq.	method			results	least 1 yr
7			$\sqrt{}$			$\sqrt{}$		$\sqrt{}$	$\sqrt{}$	$\sqrt{}$
147	V							\checkmark		
58						$\sqrt{}$		\checkmark		
128	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
30	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
202	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
14						\checkmark		\checkmark	$\sqrt{}$	$\sqrt{}$

- Ests. 373 and 109 were not eligible to export product to the U.S.
- ♦ Documents were not received from Est.211

Data Collection Instrument for Salmonella testing

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

- 1. Salmonella testing is being done in this establishment.
- 2. Carcasses are being sampled.
- 3. Ground product is being sampled.
- 4. The samples are being taken randomly.
- 5. The proper carcass site(s) and/or collection of proper product (carcass or ground) is being used for sampling.
- 6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

	1. Testing	2. Carcasses	3. Ground	4. Samples	5. Proper site	6. Violative
Est. #	as required	are sampled	product is	are taken	and/or	est's stop
			sampled	randomly	proper prod.	operations
38	$\sqrt{}$	N/A	$\sqrt{}$	$\sqrt{}$	N/A	$\sqrt{}$
604	$\sqrt{}$	$\sqrt{}$	N/A	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$
270A	$\sqrt{}$	$\sqrt{}$	N/A	N	$\sqrt{}$	$\sqrt{}$
401		V	N/A		V	$\sqrt{}$
599	$\sqrt{}$	$\sqrt{}$	N/A	N	$\sqrt{}$	$\sqrt{}$
545	$\sqrt{}$	$\sqrt{}$	N/A	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$
129	$\sqrt{}$	$\sqrt{}$	N/A	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$
75	$\sqrt{}$	$\sqrt{}$	N/A	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$
251	V	V	N/A	V	V	V

- The method used for Salmonella testing was not random in Est.270A. Corrected immediately by the establishment officials.
- The Salmonella carcass selection was not following random selection in Est.599.

Documentation was also audited from the following establishments that were not visited onsite, during the centralized document audit:

	1. Testing	2. Carcasses	3. Ground	4. Samples	5. Proper site	6. Violative
Est. #	as required	are sampled	product is	are taken	and/or	est's stop
			sampled	randomly	proper prod.	operations
7	$\sqrt{}$	$\sqrt{}$	N/A		$\sqrt{}$	$\sqrt{}$
147	V		N/A	V	$\sqrt{}$	$\sqrt{}$
58	V	$\sqrt{}$	N/A	√	V	$\sqrt{}$
128	$\sqrt{}$	N/A	$\sqrt{}$	$\sqrt{}$	V	$\sqrt{}$
30	N/A	N/A	N/A	N/A	N/A	N/A
202	N/A	N/A	N/A	N/A	N/A	N/A
14	V	V	N/A	V	V	V

- Ests. 373 and 109 were not eligible to export product to the U.S.
- ♦ Documents were not received from Est.211